

FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

EV52465798US  
Express Mail Label NumberMay 17, 2005  
Date of Deposit

Form PTO-1390-MOD (REV 10-96)		U. S. Department of Commerce Patent and Trademark Office	ATTORNEY'S DOCKET NUMBER TX/4-32544A
<b>TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371</b>			U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 10/528,688
INTERNATIONAL APPLICATION NO. PCT/EP2003/010579	INTERNATIONAL FILING DATE 23 September 2003 (23.09.03)	PRIORITY DATE CLAIMED 24 September 2002 (24.09.02)	
TITLE OF INVENTION SPHINGOSINE-1-PHOSPHATE RECEPTOR AGONISTS IN THE TREATMENT OF DEMYELINATING DISORDERS			
APPLICANT(S) FOR DO/EO/US FOSTER ET AL.			

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☐ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☒ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☐ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☐ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
  - a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☐ has been transmitted by the International Bureau. (See Form PCT/IB/308)
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)).
  - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☐ have been transmitted by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☐ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
9. ☒ Three executed Declarations and Powers of Attorney (original or copy) (35 U.S.C. 371(c)(4)).
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern document(s) or information included.

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☐ A FIRST preliminary amendment.  
☐ A SECOND or SUBSEQUENT preliminary amendment.
14. ☐ An Application Data Sheet under 37 CFR 1.76.
15. ☐ A substitute specification.
16. ☐ A change of power of attorney and/or address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821-1.825.
18. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the International application under 35 U.S.C. 154(d)(4).
20. ☐ Other items or information:


U.S. APPLICATION NO. (if known, see 37 CFR 1.5) <b>10/528,688</b>		INTERNATIONAL APPLICATION NO. <b>PCT/EP2003/010579</b>		ATTORNEY'S DOCKET NUMBER <b>TX/4-32544A</b>	
<p>The following fees are submitted:</p> <p>21. Basic national fee. .... \$</p> <p>22. Examination Fee              If International preliminary examination report was prepared by USPTO              and all claims satisfy provisions of PCT Article 33(1)-(4) ..... \$              All other situations. .... \$</p> <p>23. Search fee              If Search fee (37 CFR 1.445(a)(2)) has been paid on the international              application to the USPTO as an International Searching Authority. .... \$              If International Search Report was prepared and provided to the Office. ... \$              All other situations. .... \$</p>				<p><b>CALCULATIONS PTO USE ONLY</b></p>	
<b>TOTAL OF 21, 22 AND 23 =</b>				<b>\$ 0</b>	
Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE		
- 100 =	/50 =		X \$ 250	\$	
Surcharge of \$130 for furnishing the oath of declaration later than <input checked="" type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				<b>\$ 130</b>	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	- 20 =		X \$ 50	\$	
Independent claims	- 3 =		X \$ 200	\$	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$ 360	\$	
<b>TOTAL OF ABOVE CALCULATIONS =</b>				<b>\$ 130</b>	
Reduction of 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28).				<b>\$</b>	
<b>SUBTOTAL =</b>				<b>\$ 130</b>	
Processing fee of \$130 for furnishing the English translation later than <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				<b>\$</b>	
<b>TOTAL NATIONAL FEE =</b>				<b>\$ 130</b>	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40 per property				<b>\$</b>	
<b>TOTAL FEES ENCLOSED =</b>				<b>\$ 130</b>	
				Amount to be: refunded	\$
				charged	\$

- a. ☐ A check in the amount of \$\_\_\_\_\_ to cover the above fees is enclosed.
- b. ☒ Please charge Deposit Account No. 19-0134 in the name of Novartis in the amount of \$130 to cover the above fees. A duplicate copy of this form is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 19-0134 in the name of Novartis.

**NOTE:** Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

Send all correspondence to the address associated with Customer No. 001095, which is currently:

Novartis  
 Corporate Intellectual Property  
 One Health Plaza, Building 104  
 East Hanover, NJ 07936-1080

  
 Thomas R. Savitsky  
 Attorney for Applicants  
 Reg. No. 31,661  
 (862) 778-7909

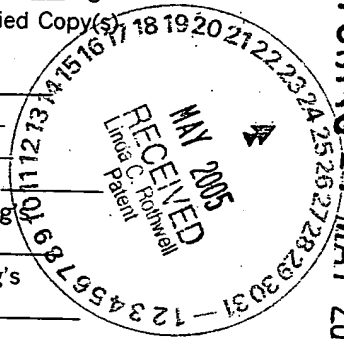
Case No. TX/4-32544A  
Application No. 10/528,688  
Mailing Date: May 17, 2005  
Due Date: \_\_\_\_\_

Express Mail No.: EV 524615798US

The Patent & Trademark Office acknowledges, and has stamped hereon the date of receipt of the items checked below:

- ☐ Amendment/Response/Letter - Fee \$ \_\_\_\_\_
- ☐ Appln. Filing Papers - Fee \$ \_\_\_\_\_
  - ☐ PCT National Stage
  - ☐ Provisional Application
  - ☐ RCE ☐ DIV ☐ CONT ☐ CIP
  - ☐ Specification \_\_\_\_\_ Pg's
- ☒ Executed/Unexecuted Decl. - Fee \$ 130 *(3 original decs)*
  - ☐ Missing Parts/Missing Req.
- ☐ Preliminary Amendment \_\_\_\_\_ Pg's
- ☐ Claim of Priority ☐ Certified Copy(s) \_\_\_\_\_
- ☐ Amendment After Final
- ☐ Notice of Appeal - Fee \$ \_\_\_\_\_
- ☐ Appeal Brief - Fee \$ \_\_\_\_\_
- ☐ Issue Fee Payment \$ \_\_\_\_\_
- ☐ Assignment Rec. Req. - Fee \$ \_\_\_\_\_
- ☐ Formal Drawings \_\_\_\_\_ Pg's
- ☐ IDS \_\_\_\_\_ Pg's - Fee \$ \_\_\_\_\_
- ☐ PTO-1449 Form \_\_\_\_\_ Pg's
- ☐ Pet. for Ext. of Time - Fee \$ \_\_\_\_\_
- ☐ Application Data Sheet
- ☐ Seq. Listings \_\_\_\_\_ Pg's/Seq. Disk
- ☐

TRS  
Initials





## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address: COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
 www.uspto.gov

APPL NO.	FILING OR 371 (c) DATE	ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	DRAWINGS	TOT CLMS	IND CLMS
10/528,688	03/21/2005	1614	1230	TX/4-32544A		11	4

1095  
 NOVARTIS  
 CORPORATE INTELLECTUAL PROPERTY  
 ONE HEALTH PLAZA 104/3  
 EAST HANOVER, NJ 07936-1080

*wrong filing date*

*TRS*

CONFIRMATION NO. 4630

## FILING RECEIPT



\*OC000000017190489\*

Date Mailed: 10/13/2005

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

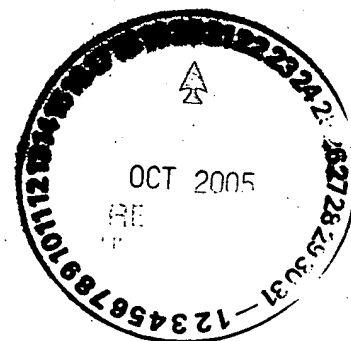
## Applicant(s)

Carolyn Ann Foster, Wien, AUSTRALIA;  
 Peter C Hiestand, Allschwil, AUSTRALIA;  
 Paul William Glue, Flemington, NJ;

**Power of Attorney:** The patent practitioners associated with Customer Number 1095.

## Domestic Priority data as claimed by applicant

This application is a 371 of PCT/EP03/10579 09/23/2003  
 which claims benefit of 60/413,172 09/24/2002  
 and claims benefit of 60/485,132 07/07/2003



## Foreign Applications

**Projected Publication Date:** To Be Determined - pending completion of Security Review

**Non-Publication Request:** No

**Early Publication Request:** No

**Title**

Organic compounds

**Preliminary Class**

514

**PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES**

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

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**LICENSE FOR FOREIGN FILING UNDER  
Title 35, United States Code, Section 184  
Title 37, Code of Federal Regulations, 5.11 & 5.15**

**GRANTED**

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

#### **NOT GRANTED**

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

EV584613664 US  
Express Mail Label NumberNovember 14, 2005  
Date of Deposit

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE PCT NATIONAL STAGE APPLICATION OF  
FOSTER ET AL.

INTERNATIONAL APPLICATION NO: PCT/EP2003/010579

FILED: 23 SEPTEMBER 2003

U.S. APPLICATION NO: 10/528,688

35 USC §371 DATE: 17 MAY 2005

FOR: SPHINGOSINE-1-PHOSPHATE RECEPTOR AGONISTS IN THE  
TREATMENT OF DEMYELINATING DISORDERS

**Mail Stop PCT**

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

**Attention: Donna Greene**

LETTER CORRECTING NOTICE OF ACCEPTANCE OF APPLICATION UNDER 35 USC 371  
AND OFFICIAL FILING RECEIPT

Sir:

The official filing receipt received in the above-identified application erroneously lists the filing date. Upon review of the instant application, Applicants noted that the **Notice of Acceptance of Application under 35 USC 371 (NOAOA)** (a copy is enclosed herewith) listed the 371 date incorrectly.

When Applicants filed the PCT application in the national stage on March 21, 2005, an unsigned Declaration was sent to the Patent & Trademark Office (PTO). On **May 17, 2005**, the executed Declaration was sent to the PTO as a second submission item with Form PTO-1390-MOD by Express Mail (a copy is enclosed herewith). Therefore, the section "DATE OF RECEIPT OF 35 USC 371(c)(1), (c)(2) and (c)(4) REQUIREMENTS" on the (NOAOA) should read: May 17, 2005 not March 21, 2005 when all requirements were received. The May 17, 2005 date should be the **correct filing date on the filing receipt**. Also, under the list of the items received, the date when the executed Oath or Declaration was filed should read: May 17,

2005. Please make the necessary changes on the (NOAOA) and on the filing receipt regarding the filing date to avoid problems in the future.

Please issue a corrected filing receipt listing the filing date as follows:

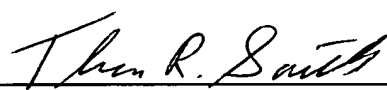
-- May 17, 2005 --.

A copy of the filing receipt with the correction noted is enclosed.

No fee is believed to be required by this request for a corrected filing receipt.

Respectfully submitted,

Novartis  
Corporate Intellectual Property  
One Health Plaza, Building 104  
East Hanover, NJ 07936-1080  
(862) 778-7909  
TRS/dd

  
\_\_\_\_\_  
Thomas R. Savitsky  
Attorney for Applicants  
Reg. No. 31,661

Encl.: copy of filing receipt  
copy of For PTO-1390-MOD  
copy of NOAOA

Date: *November 10, 2005*



PCT



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

U.S. APPLICATION NUMBER NO. 10/528,688	FIRST NAMED APPLICANT Carolyn Ann Foster	ATTY. DOCKET NO. TX/4-32544A
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INTERNATIONAL APPLICATION NO.
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PCT/EP03/10579

I.A. FILING DATE 09/23/2003	PRIORITY DATE 09/24/2002
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1095  
NOVARTIS  
CORPORATE INTELLECTUAL PROPERTY  
ONE HEALTH PLAZA 104/3  
EAST HANOVER, NJ 07936-1080

TRS

CONFIRMATION NO. 4630

371 ACCEPTANCE LETTER



\*OC000000017190490\*

Date Mailed: 10/13/2005

## NOTICE OF ACCEPTANCE OF APPLICATION UNDER 35 U.S.C 371 AND 37 CFR 1.495

The applicant is hereby advised that the United States Patent and Trademark Office in its capacity as a Designated / Elected Office (37 CFR 1.495), has determined that the above identified international application has met the requirements of 35 U.S.C. 371, and is ACCEPTED for national patentability examination in the United States Patent and Trademark Office.

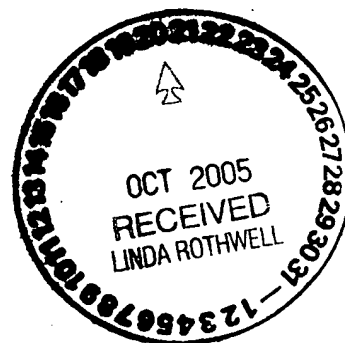
The United States Application Number assigned to the application is shown above and the relevant dates are:

DATE OF RECEIPT OF 35-U.S.C. 371(c)(1), (c)(2) and (c)(4) REQUIREMENTS	DATE OF COMPLETION OF ALL 35 U.S.C. 371 REQUIREMENTS
<u>03/21/2005</u> <i>wrong 371 date</i>	<u>05/17/2005</u>

A Filing Receipt (PTO-103X) will be issued for the present application in due course. **THE DATE APPEARING ON THE FILING RECEIPT AS THE " FILING DATE" IS THE DATE ON WHICH THE LAST OF THE 35 U.S.C. 371 (c)(1), (c)(2) and (c)(4) REQUIREMENTS HAS BEEN RECEIVED IN THE OFFICE. THIS DATE IS SHOWN ABOVE.** The filing date of the above identified application is the international filing date of the international application (Article 11(3) and 35 U.S.C. 363). Once the Filing Receipt has been received, send all correspondence to the Group Art Unit designated thereon.

The following items have been received:

- Copy of the International Application filed on 03/21/2005
- Copy of the International Search Report filed on 03/21/2005
- Copy of IPE Report filed on 03/21/2005
- Preliminary Amendments filed on 03/21/2005
- Information Disclosure Statements filed on 03/21/2005
- Oath or Declaration filed on 03/21/2005
- Copy of references cited in ISR filed on 03/21/2005
- U.S. Basic National Fees filed on 03/21/2005
- Priority Documents filed on 03/21/2005
- Power of Attorney filed on 03/21/2005



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Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

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DEBORAH D WILLIAMS

Telephone: (703) 308-9140 EXT 205

**PART 1 - ATTORNEY/APPLICANT COPY**

FORM PCT/DO/EO/903 (371 Acceptance Notice)